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## IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF VIRGINIA ABINGDON DIVISION

JULIA COUDURY, CLERK BY: JULIA DEPUTY CLERK

UNITED STATES

Criminal No. 1:12 CR 26

v.

Violations: 21 U.S.C. §§ 331(a), 333(a)(1),

ABBOTT LABORATORIES

352(a) & 352(f)(1)

## **INFORMATION**

## **COUNT ONE**

Introduction of Misbranded Drug into Interstate Commerce 21 U.S.C. §§ 331(a), 333(a)(1), 352(a) and 352(f)(1)

The United States Attorney charges that:

- 1. The Agreed Statement of Facts is alleged, incorporated by reference and made a part of this Count.
- 2. From in or about January 1998 to in or about December 2006, ABBOTT LABORATORIES introduced and delivered for introduction into interstate commerce and caused the introduction and delivery for introduction into interstate commerce from Illinois and Puerto Rico to various locations throughout the United States, including the Western District of Virginia, quantities of Depakote (a/k/a Depakote DR), Depakote ER, and Depakote Sprinkle (hereinafter collectively referred to as "Depakote") that were misbranded.
- 3. From in or about January 1998 to in or about December 2006, Depakote was misbranded, within the meaning of Title 21, United States Code, Section 352(f)(1), in that the labeling lacked adequate directions for use for the control of agitation, aggression, and other behavioral symptoms exhibited by elderly patients with dementia.

Information United States v. Abbott Laboratories Attachment A to Plea Agreement

- 4. From in or about January 2002 to in or about December 2006, Depakote was misbranded, within the meaning of Title 21, United States Code, Section 352(f)(1), in that the labeling lacked adequate directions for use for the treatment of schizophrenia.
- 5. From in or about December 2004 to in or about December 2006, Depakote was misbranded, within the meaning of Title 21, United States Code, Section 352(a), in that the drugs' labeling was misleading for use for the (a) control of agitation, aggression, and other behavioral symptoms exhibited by elderly patients with dementia and (b) treatment of schizophrenia.
- 6. All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), 352(a) and 352(f)(1).

## **NOTICE OF FORFEITURE**

- 1. Upon conviction of the offense alleged in this Information, ABBOTT LABORATORIES shall forfeit to the United States quantities of Depakote, Depakote ER and Depakote Sprinkle that were misbranded when introduced into interstate commerce, pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461.
- 2. Because the above-described forfeitable property, as a result of the acts of the defendant, has been transferred or sold to third parties and cannot be located upon the exercise of due diligence, it is the intent of the United States to seek forfeiture of \$198,500,000.00 (one hundred ninety-eight million five hundred thousand dollars), pursuant to 21 U.S.C. § 853(p).

Date:

TIMOTHY J. HEARHY

United States Attorney

Western District of Virginia

Rick A. Mountcastle, Assistant United States Attorney

Randy Ramseyer, Assistant United States Attorney

Carol Wallack, Trial Attorney, U.S. Dept. Of Justice, Consumer Protection Branch Lauren Bell, Trial Attorney, U.S. Dept. Of Justice, Consumer Protection Branch Jill Furman, Assistant Director, U.S. Dept. of Justice, Consumer Protection Branch